UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Joel Schneider, Magistrate Judge

MANUFACTURER DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

Plaintiffs have filed three master complaints ("Complaints")[1] seeking to assert claims for personal injury, economic loss or medical monitoring on behalf of themselves or putative classes of consumers allegedly exposed to nitrosamine-containing valsartan and valsartan combination drugs (collectively, "VCDs").[2] Rather than supply the requisite "short and plain statement" of claims for relief contemplated by Rule 8, the Complaints exemplify shotgun pleading. They collectively span nearly 1,700 paragraphs and close to 400 pages, asserting approximately three dozen claims between them on behalf of dozens of individual plaintiffs and putative statewide and nationwide classes of consumers directed against over 40 separate defendants ("Defendants") lumped together in group allegations.[3] The claims encompass federal and state statutory law, common law and

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[1] The Complaints are referred to as the "PIMC," for the Master Personal Injury Complaint (ECF No. 122), the "ELMC," for the Consolidated Second Amended Economic Class Action Complaint (ECF No. 398), and the "MMMC," for the Consolidated Amended Medical Monitoring Class Action Complaint (ECF No. 123).

[2] On December 18, 2019, this MDL was expanded by the JPML to include losartan and irbesartan. ECF No. 285. Master complaints asserting claims arising out of alleged impurities in losartan and irbesartan have not yet been filed. Consequently, Defendants' three omnibus Motions to Dismiss challenge only the claims involving valsartan. Defendants reserve their right to file motions to dismiss any master complaints filed as to losartan and irbesartan.

[3] The Complaints should be dismissed for this reason alone. *See D'Addario v. Johnson & Johnson*, No. 3:10-cv-15627, 2020 WL 3546750, at *6 (D.N.J. June 30, 2020) ("Courts in this district generally agree that this type of 'group pleading' does

equitable theories traversing federal law and the common law of all 50 states, the District of Columbia, and Puerto Rico—many of which are unrepresented by any plaintiff.

Huge swaths of Plaintiffs' claims are unsustainable as a matter of law, and their sheer volume threatens to encumber these proceedings with years of wholly unnecessary discovery and motion practice. Neither Defendants nor the Court should be burdened by jurisdictionally and facially insufficient claims, which comprise the bulk of the Complaints yet cannot meet the threshold pleading obligations under the Federal Rules of Civil Procedure. Plaintiffs are not permitted to treat these proceedings as "some kind of judicial border country, where the rules are few and the law rarely makes an appearance." *In re Nat'l Prescription Opiate Litig.*, 956 F.3d 838, 844 (6th Cir. 2020). Rules 8, 9, and 12 are not "merely hortatory" in multi-district litigation; they must be followed. *Id*.

Accordingly, the Manufacturer Defendants[4] bring this motion to dismiss to

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not satisfy Rule 8, because it does not place Defendants on notice of the claims against each of them.") (quoting *Sheeran v. Blyth Shipholding S.A.*, No. 1:14-cv-5482, 2015 WL 9048979, at *3 (D.N.J. Dec. 16, 2016)).

[4] Plaintiffs' pleadings oversimplify the complexities of the generic drug distribution process by blurring key distinctions between Manufacturer Defendants and downstream Defendants such as distributors and re-packagers. These downstream Defendants have no involvement in the manufacturing process; nor do they advertise or make statements about generic drugs to consumers. Subject to these distinctions, all distributors and re-packagers in the MDL join in the Manufacturer Defendants' arguments for dismissal. Additionally, Aurobindo Pharma, USA, Inc. ("APUSA"),

clear away Plaintiffs' deficient claims (the "Motion"), as follows:

- **Lack of Standing**: The Court should dismiss the ELMC in its entirety for failure to allege an injury-in-fact.[5] The Court should further dismiss all Defendants in the ELMC and MMMC to whom Plaintiffs have failed to trace their injuries, and all claims alleged under the laws of states not represented by any Plaintiff. *See* Charts at 10–13. The Court should also permit Defendants contesting personal jurisdiction to file and to be heard on their motions, as required by Rule 12(b)(2). *See infra* n.12; Charts at 14–15.

- **Preemption and Primary Jurisdiction**: The Court should dismiss the Complaints' claims for negligence *per se*, strict liability design defect, breach of express warranty, fraudulent and negligent misstatement, and state consumer protection acts, as preempted by federal law. *See* Charts at 7–9. Then, based on primary jurisdiction, the Court should dismiss or stay, and abstain from deciding, Plaintiffs' claims for breach of implied warranty, strict liability failure-to-warn, negligence and

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Hetero USA, Inc. ("Hetero USA"), and Prinston Pharmaceutical Inc. ("Prinston") (collectively, the "FDA Liaison Defendants") join in the Manufacturer Defendants' arguments for dismissal and further move to dismiss Plaintiffs' claims as discussed at Section VI herein. Further, concurrently with this submission, the Pharmacy Defendants and Wholesaler Defendants are submitting motions to dismiss, and Manufacturer Defendants hereby join in those briefs and incorporate them by reference.

[5] Throughout this brief, the Manufacturer Defendants refer to charts summarizing deficient allegations or identifying various state law authorities. Those charts are attached hereto in a Compendium of Charts Referenced in Manufacturer Defendants' Memorandum of Law in Support of Manufacturer Defendants' Motion to Dismiss ("Charts"). All authorities cited in the Charts are hereby expressly incorporated by reference into Manufacturer Defendants' motion to dismiss and this memorandum of law in support thereof. For the Court's convenience, all non-reported and unpublished cases cited in this brief or the Charts are compiled in two compendiums submitted herewith: (1) Compendium of Unreported or Unpublished Authorities Cited in Manufacturer Defendants' Memorandum of Law in Support of Their Motion to Dismiss; and (2) Compendium of Unreported or Unpublished Authorities Cited in the Manufacturer Defendants' Compendium of Charts.

manufacturing defect until the U.S. Food & Drug Administration ("FDA") completes its pending agency action relating to VCDs.

- **Subsumption**: The Court should dismiss the common law and state consumer protection act claims of all New Jersey Plaintiffs because their claims are subsumed by the New Jersey Products Liability Act ("NJPLA"), together with the claims of all Plaintiffs from states with similar statutes. *See* Charts at 16–19.

- **Claim-Specific Deficiencies**: The Court should dismiss or stay most of the Complaints' myriad enumerated claims, *e.g.*, fraud, unjust enrichment, negligence *per se*, punitive damages, based on their claim-specific legal and facial deficiencies. *See* Charts at 20–67.

For each of these reasons, the Court should dismiss the Complaints in whole or, at least, in part. Holding Plaintiffs to their pleading obligations now will end this action, or greatly simplify the pleadings by eliminating unviable claims and pave the way for a more focused, just and efficient proceeding.

FACTUAL BACKGROUND

I. VALSARTAN RECALLS IN THE UNITED STATES

These cases arise out of certain voluntary recalls of VCDs in the United States. VCDs are the generic versions of the branded angiotensin II receptor blocker ("ARB") drugs Diovan®, Diovan HCT®, Exforge®, and Exforge HCT®, which are all primarily used to treat hypertension and lessen the risk of adverse cardiovascular events. PIMC ¶ 9.

On July 13, 2018, Defendant Zhejiang Huahai Pharmaceutical Co, Ltd. announced the first voluntary recall of VCDs, followed by other Manufacturer Defendants, after discovering that certain valsartan active pharmaceutical ingredient

("API") contained trace amounts of N-nitrosodimethylamine ("NDMA"). *Id.* ¶¶ 170 & n.63, 177 & n.70. Some VCDs were further recalled starting in November 2018 for potentially containing trace amounts of N-Nitrosodiethylamine ("NDEA"). *Id.* ¶ 180 & n.73.

NDMA and NDEA are common organic chemical compounds called "nitrosamines" to which humans can be exposed through ingestion of water and various foods. PIMC ¶¶ 150, 179. Nitrosamines are potential byproducts of the manufacturing process for valsartan API,[6] but not all batches of ARBs contain nitrosamines.[7]

In announcing its investigation into the nitrosamine impurities in VCDs, FDA acknowledged that "NDMA's properties make it difficult to find[,]" and that, until the recall, the FDA had not developed a test that could identify nitrosamines in

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[6] *See* FDA Statement on the Agency's List of Known Nitrosamine-Free Valsartan and ARB Class Medicines (April 4, 2019), *accessible at https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-Valsartan-and-arb-class-medicines-part-agencys*. The Court may take judicial notice of FDA's public records. *Otsuka Pharma Co. v. Torrent Pharm. Ltd.*, 118 F. Supp. 3d 646, 655 n.7 (D.N.J. 2015). This Court can also consider materials expressly incorporated into the Complaints (*see, e.g.*, ELMC at nn.6, 48, 52, 73) and integral to Plaintiffs' claims. *See Davis v. Wells Fargo*, 824 F.3d 333, 351 (3d Cir. 2016); *Donovan v. Pub. Policy Ctr. of New Jersey*, No. 05-1181, 2006 WL 1373230, at *2 (D.N.J. May 17, 2006).

[7] *See* FDA's Assessment of Currently Marketed ARB Drug Products, *accessible at https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications*.

valsartan.[8] Given the very low risk of any injury that might occur from nitrosamine exposure in VCDs, FDA emphasized that patients should keep taking their current VCDs, even if it has been recalled, until they speak with their physicians because the risk of not taking their VCDs "greatly outweighs the potential risk of exposure to trace amounts of nitrosamines."[9]

FDA has since "clarified the risk and scope of exposure" to patients:

> [T]he actual risk to patients is likely much lower than our estimates, which reflect a scientific assessment of the highest possible exposure. We initially estimated that if 8,000 people took the highest valsartan dose (320 mg) containing [NDMA] from the recalled batches daily for four years, there may be one additional case of cancer over the lifetimes of those 8,000 people. In reality, the vast majority of patients exposed to NDMA through ARBs received much smaller amounts of the impurity than this worst-case scenario, and, since not all ARBs are affected, it's very likely that a patient taking an ARB for four years would not have always received one of the affected products.[10]

II. PLAINTIFFS' ALLEGATIONS

The PIMC asserts claims on behalf of consumers who allegedly purchased

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[8] *See* FDA's Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings (Aug. 30, 2018), *accessible at https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-impurities-and-recalls-and-update-fdas-current.*

[9] *See* Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications (Aug. 28, 2019), accessible at *https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications*.

[10] *See supra* n.9.

and consumed VCDs and developed cancer they attribute to those products. *See* Charts at 4 (identifying claims asserted in PIMC). The ELMC brings claims on behalf of consumers who allegedly purchased nitrosamine-containing VCDs and third party payors who purchased or made reimbursements related to such VCDs. ELMC ¶ 4; *see* Charts at 5 (identifying claims asserted in ELMC). The MMMC asserts medical monitoring claims on behalf of a putative nationwide class of individuals who allegedly purchased and consumed nitrosamine-containing VCDs and allege "clinical and genetic injury" that they claim increases their risk of developing cancer. MMMC ¶¶ 1, 10-19 390; *see* Charts at 6 (identifying claims asserted in MMMC).

ARGUMENT

I. LEGAL STANDARDS

A motion to dismiss for lack of standing is brought under Rule 12(b)(1) because standing is a prerequisite to the Court's subject matter jurisdiction under Article III. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012). A facial challenge to standing is evaluated under the same legal standard as a Rule 12(b)(6) motion. *Id*. Plaintiff "bears the burden of establishing" standing. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is

plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Plaintiffs are required to allege well-pleaded, non-conclusory facts supporting each element of each of their claims. *See Sich v. Pfizer Pharm.*, No. 1:17-cv-2828, 2017 WL 4407930, at *2 (D.N.J. Oct. 4, 2017) (Kugler, J.).

Operative and administrative master complaints[11] are both subject to dismissal under Rule 12. *See, e.g.*, *In re Katrina Canal Breaches Litig.*, 309 F. App'x 836, 839 (5th Cir. 2009); *In re Digitek Prods. Liab. Litig.*, No. 2:08-md-01968, 2009 WL 2433468 (S.D. W. Va. Aug. 3, 2009). Rule 12 tests the sufficiency of the allegations in an administrative master complaint that are common to all plaintiffs, and tests the sufficiency of the operative master complaint itself. *See In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.,* No. 11-c-5468, 2012 WL 3582708, at *4 (N.D. Ill. Aug. 16, 2012); *In re Refrigerant Compressors*, 731 F.3d at 590.

II. THE ELMC AND MMMC SHOULD BE DISMISSED FOR LACK OF ARTICLE III STANDING.

The ELMC and MMMC fail to satisfy their threshold burden of pleading

[11] An operative master complaint supersedes prior individual complaints, merging those actions for the duration of the MDL. *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 413 (2015). An administrative master complaint summarizes the claims presented in individual actions for purposes of managing the MDL, with individual complaints retaining separate legal existence. *In re Gen. Motors LLC Ignition Switch Litig.*, No. 14-md-2543, 2015 WL 3619584, at *7 (S.D.N.Y. June 10, 2015); *In re Refrigerant Compressors Antitrust Litig.*, 731 F.3d 586, 590 (6th Cir. 2013). Here, the PIMC is administrative, and the ELMC and MMMC are operative.

Article III standing because they fail in whole or in part to allege the requisite elements of an injury-in-fact and traceability and seek to assert claims under the laws of states in which Plaintiffs do not reside and were not injured. For these reasons, the Court should dismiss Plaintiffs' claims in whole or in part under Rule 12(b)(1) for lack of standing.[12]

"[T]o survive a motion to dismiss for lack of standing, a plaintiff 'must allege

[12] The Court directed that Defendants' Motions to Dismiss should exclude challenging personal jurisdiction under Rule 12(b)(2), and has instructed Defendants to prioritize briefing other substantive issues (while preserving the issue of personal jurisdiction for later). Defendants reserve all applicable personal jurisdiction defenses pursuant to Rule 12(h)(1)(A), but again respectfully urge the Court to grant leave and to set a schedule for Defendants to file a supplemental 15-page memorandum addressing their personal jurisdiction defenses now, so as to avoid potential legal error as to Defendants with viable personal jurisdiction defenses. Defendants are mindful of this Court's order, but as the Sixth Circuit recently observed in *In re Nat'l Prescription Opiate Litig.*, 956 F.3d at 844, "Civil Rule 12(b) states that 'a party *may* assert' the defenses enumerated therein 'by motion,' which means that the district court may *not* refuse to adjudicate motions properly filed under that Rule." *Id.* at 846 (emphases in original). As one example of the significance and breadth of the personal jurisdiction issues in this case, the ELMC and MMMC name several out-of-state Defendants from whom *none* of the named class representative Plaintiffs allege that they made purchases in New Jersey, as required for this Court to exercise personal jurisdiction. *See* Charts at 14–15; *Bristol-Myers Squibb Co. v. Super. Ct. of Cal.*, 137 S. Ct. 1773, 1780–1781 (2017); *Horowitz v. AT&T, Inc.*, No. 3:17-cv-4827, 2018 WL 1942525, at *15 (D.N.J. Apr. 25, 2018). The Complaints also name overseas Defendants lacking the requisite jurisdictional connection to the United States altogether, over whom this Court lacks personal jurisdiction. *See Asahi Metal Indus. Co. v. Super. Ct. of Cal.*, 480 U.S. 102, 112–116 (1987). These facial challenges to personal jurisdiction are determinable on the pleadings and involve straightforward defects that the Court can and should decide now to eliminate improperly joined defendants and claims.

facts that affirmatively and plausibly suggest that it has standing to sue.' Speculative or conjectural assertions are not sufficient." *Finkelman v. Nat'l Football League*, 810 F.3d 187, 194 (3d Cir. 2016) (citation omitted). To satisfy Article III standing, a plaintiff must allege: "(1) an injury-in-fact that is actual or imminent and concrete and particularized, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's challenged conduct, and (3) is likely to be redressed by a favorable judicial decision." *Koronthaly v. L'Oreal USA, Inc.*, 374 F. App'x 257, 259 (3d Cir. 2010). Plaintiffs have not met their burden.

A. The ELMC Does Not Allege an Injury-in-Fact.

The ELMC is devoid of allegations of non-speculative harm sufficient to allege an injury-in-fact, which requires a plaintiff to "allege an injury to himself that is 'distinct and palpable,' as opposed to merely '[a]bstract,' and the alleged harm must be actual or imminent, not 'conjectural' or 'hypothetical.'" *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (internal quotations omitted). The ELMC makes no allegation of physical injury or product malfunction and it provides no basis for the Court to value any purported economic injury. At most, Plaintiffs allege regret and distress as a result of ingesting VCDs they fear might cause them harm in the future. *See* ELMC ¶ 372. They further allege the VCDs were "worthless" and thereby caused them financial harm. These allegations, however, fall well short of the threshold to plead Article III standing based on an injury-in-fact.

The only allegation in the ELMC that approaches an assertion of physical harm is that consumers were allegedly "exposed to a non-bargained for carcinogenic agent with mutagenic properties that operates at the cellular and sub-cellular levels, and ***may give rise to future potential health consequences***[.]" *Id.* (emphasis added). However, "the fear of future injury is legally insufficient to confer standing." *James v. Johnson & Johnson Consumer Co., Inc.*, No. 2:10-cv-03049, 2011 WL 198026, at *2 (D.N.J. Jan. 20, 2011); *see also Hubert v. Gen. Nutrition Corp.*, No. 2:15-cv-01391, 2017 WL 3971912, at *8 (W.D. Pa. Sept. 8, 2017) ("[A]pprehension concerning future health consequences is insufficient to establish an injury-in-fact."). Given FDA's clarification of "the risk and scope of exposure" to patients resulting from taking the allegedly impure VCDs, *see supra* at 9, any allegation of future injury is implausible.

The ELMC also does not and cannot allege that the VCDs stopped working due to the alleged impurity. On the contrary, it concedes "FDA advised people to continue taking" the allegedly impure VCDs because of "the risks associated with untreated high blood pressure." *Id.* ¶ 373. Absent an allegation that Plaintiffs were injured by the VCDs or failed to receive their anticipated medical benefit, plaintiffs lack a theory of injury-in-fact based on a failure to receive the bargained-for benefit. *See Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320–321 (5th Cir. 2002) (holding plaintiffs lacked an injury-in-fact as to a withdrawn prescription painkiller because

they did not allege that they themselves were injured by the prescription drug at issue or that it was defective as to them); *Medley v. Johnson & Johnson Consumer Cos.*, No. 2:10-cv-2291, 2011 WL 159674, at *2 (D.N.J. Jan. 18, 2011) (holding plaintiffs lacked an injury-in-fact from their purchase of baby shampoo containing a toxic ingredient because "the product worked as intended, meaning that the hair of Plaintiff's children was cleansed, and their eyes and skin were not irritated"); *Hughes v. Chattem, Inc.*, 818 F. Supp. 2d 1112, 1119 (S.D. Ind. 2011) (holding plaintiffs did not "come[] close to establishing an injury in fact" as a result of purchasing supplements based on report showing "they *may* experience future harm from their limited exposure to hexavalent chromium, and . . . now wish[ing] they had not purchased" the supplements).

That leaves the ELMC's conclusory assertion that the VCDs were "worthless" due to the nitrosamine impurity. At the outset, because the ELMC lacks any allegation of physical injury or failure of the anticipated benefit, it has no plausible factual basis for the assertion that Plaintiffs purchased a "worthless" medication. Without an allegation that the VCDs "failed to work for [their] intended purpose or [were] worth objectively less than what one could reasonably expect," Plaintiffs cannot demonstrate a concrete injury-in-fact. *Koronthaly*, 374 F. App'x at 259. A plaintiff "who has entirely consumed a product that has functioned for her as expected" does not "suffer an economic injury solely because she now sincerely

wishes that she had not purchased that product[.]" *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 280-81 (3d Cir. 2018). The ELMC does nothing more than "pair a conclusory assertion of money lost with a request that a defendant pay up," leaving "no economic injury" giving rise to standing. *Id*. at 288.

But even if the ELMC articulated an objective basis to conclude the VCDs were worth objectively less, it still alleges no facts from which the Court could value the purported economic injury. To establish an economic injury-in-fact, a plaintiff must "allege facts that would permit a factfinder *to value the purported injury* at something more than zero dollars without resorting to mere conjecture." *Id.* at 285 (emphasis added). That allegation is missing here. Once a product has been purchased and consumed, and has functioned as intended without causing any adverse health consequences, the user can hypothesize no factual basis to value an actual injury. *See James*, 2011 WL 198026, at *2; *Bowman v. RAM Med., Inc.*, No. 10-4403, 2012 WL 1964452, at *1, *3 (D.N.J. May 31, 2012); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 172, 176 (D.D.C. 2003).

Numerous authorities demonstrate the failure of the ELMC's valuation of its injury as a "worthless" product. In *Johnson & Johnson Talcum Powder*, the Third Circuit rejected a plaintiff's claim that she was economically injured because she would not have purchased baby powder if she had known it could lead to an

increased risk of developing ovarian cancer. *Johnson & Johnson Talcum Powder*, 903 F.3d at 282. Because the plaintiff did not allege that she had developed ovarian cancer, nor that she herself suffered an increased risk of developing ovarian cancer, the court held she lacked standing to seek monetary damages because she "failed to allege that the economic benefit she received from that powder was *anything* less than the price she paid." *Id.* at 290.

Likewise, in *James*, the court rejected the plaintiffs' argument that they were economically harmed merely because they bought and used baby shampoo that was allegedly tainted with methyl chloride and thereafter "feared for the future safety of their children." *James*, 2011 WL 198026, at *2. While the court acknowledged it was probably true that the plaintiffs would not have purchased or used the baby shampoo if they had known about the alleged toxicity, "the conclusion that 'consequently, [p]laintiffs have been economically damaged' simply does not follow." *Id.* (citation omitted). The court explained:

> Once the product had been consumed, however, there was no economic injury for Plaintiffs to complain of, and the fear of future injury is legally insufficient to confer standing. Plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended, meaning that the hair of Plaintiff's children was cleansed, and their eyes and skin were not irritated.

Id.; *see also Hubert*, 2017 WL 3971912, at *8.

This case is no different. The ELMC's allegation that allegedly impure VCDs "may give rise to future health consequences" is insufficient to render the products

objectively worth less than what consumers paid. ELMC ¶ 372. The ELMC does not allege physical harm or any kind of malfunction. Nor could it, since the VCDs performed as expected and aided Plaintiffs by lowering their blood pressure and the risk of adverse health consequences arising from hypertension. For that reason, the ELMC fails to allege non-conclusory facts to support a plausible claim that Plaintiffs did not receive the benefit of their bargain or suffered any cognizable injury-in-fact capable of being valued above zero dollars.

B. The ELMC and MMMC Fail to Plead Injuries Traceable to All Defendants.

The ELMC and MMMC also fail to allege that Plaintiffs' purported harms are "properly attributed" to *all* Defendants' alleged conduct, and thus have failed to satisfy the requirement of traceability for Article III standing. *Finkelman*, 810 F.3d at 194. Complaints must connect *each* defendant to at least one injured plaintiff to satisfy this element. *See Hidalgo v. Johnson & Johnson Consumer Co., Inc.*, 148 F. Supp. 3d 285 (S.D.N.Y. 2015) ("[F]or every named defendant there must be at least one named plaintiff who can assert a claim directly against that defendant, and at that point standing is satisfied and only then will the inquiry shift to a class action analysis.") (citing 1 Newberg on Class Actions § 2:6 n.3 (4th ed. 2002)).

The ELMC and MMMC assert all claims in lumped fashion against all Defendants. Yet there are many Defendants against whom no specific factual allegations are made, much less an allegation that these Defendants manufactured

(or in the case of downstream Defendants, later supplied or sold) the VCDs purchased or consumed by any named Plaintiff. ELMC ¶¶ 11–34; MMMC ¶¶ 9–19. Because no named Plaintiff traces his or her alleged harm to the conduct of any of these Defendants, the claims against them should be dismissed for lack of standing. Defendants in this category are listed in the Charts at 10–11.

C. Plaintiffs Lack Standing to Bring Claims Across All States.

A class representative only has standing to sue under the laws of a state where she resides or was injured. *Cooper v. Medimetriks Pharms., Inc*., No. 18-11987, 2019 WL 1370414, at *4, (D.N.J. Mar. 25, 2019); *In re Magnesium Oxide Antitrust Litig.,* No. 10-cv-5943, 2011 WL 5008090 (D.N.J. Oct. 20, 2011). The ELMC and MMMC allege that the class representatives reside in 21 states[13] and do not allege that their purported injuries occurred in any other states. Nevertheless, both Complaints assert claims under the laws of all 50 states, Washington, D.C., and Puerto Rico. ELMC ¶¶ 441, 457, 545; MMMC ¶¶ 444, 459, 472. Accordingly, the claims asserted in the ELMC and MMMC under the laws of the other 31 states and territories for which no allegations establishing standing have been asserted,

[13] Specifically, the ELMC and MMMC class representatives allege that they live in California, Connecticut, Illinois, Indiana, Florida, Georgia, Kansas, Louisiana, Maryland, Massachusetts, Mississippi, New Jersey, New Mexico, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Texas, Virginia, and West Virginia. ELMC ¶¶ 11–34; MMMC ¶¶ 9–19.

identified in the Charts at 12–13, should be dismissed.

III. MOST OF THE COMPLAINTS' STATE-LAW CLAIMS ARE PREEMPTED AND THE COURT SHOULD ABSTAIN FROM DECIDING THE REMAINDER UNDER PRIMARY JURISDICTION.

Many of the Complaints' state-law claims are preempted as improper attempts to enforce the Federal Food, Drug, and Cosmetic Act ("FDCA") under state law. Only the federal government has the authority to enforce the FDCA. *See* 21 U.S.C. § 337(a). Private litigants are forbidden to bring "proceedings for the enforcement, or to restrain violations, of" the FDCA under Section 337(a) of the statute. *Id*. That prohibition applies with equal force to attempts by private litigants to enforce the FDCA indirectly under state law. *See id.* § 337(b). Because most of the Complaints' claims ultimately depend on proving a violation of the FDCA, they are squarely preempted by Section 337(a). The Court should abstain from deciding the remaining claims because they raise issues within FDA's specialized expertise under the primary jurisdiction doctrine.

A. Most of the Complaints' State-Law Claims are Disguised Attempts to Privately "Enforc[e]" or "Restrain Violations" of the FDCA.

Both direct and indirect attempts to privately enforce the FDCA are preempted under Section 337(a). *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 353 (2001). If a state-law first claim depends on establishing a violation of the FDCA, or relies on a concept or standard that only exists by virtue of the FDCA, it is

preempted as a private attempt to "enforc[e]" or "restrain violations" of the FDCA.

Congress tasked the federal government alone with balancing the complicated scientific, economic, public health and safety considerations involved in enforcing the FDCA. *See Farina v. Nokia Inc.*, 625 F.3d 97, 124 (3d Cir. 2010). In recognition of this legislative judgment, a unanimous Supreme Court has interpreted Section 337(a) to impliedly preempt state-law claims where "the existence" of the FDCA "is a critical element" of the state-law claim. *Buckman*, 531 U.S. at 353. FDA has cautioned that private litigants cannot "circumvent this straightforward prohibition" on private enforcement of the FDCA "by wrapping their FDCA enforcement claims inside some *other* cause of action." Corrected Brief for the United States as Amicus Curiae Supporting Appellee at 7, 10, *Amarin Pharma, Inc. v. ITC* (Fed. Cir. Mar. 27, 2018) (2018-1247, 2018-114) ("FDA Amicus").[14] Such claims are, "at bottom, still an action 'for the enforcement' or 'to restrain violations' of the FDCA." *Id.* at 10; *see also Abicht v. PLIVA, Inc.*, No. 12-1278, 2013 WL 141724 at *2–3 (D. Minn. Jan. 9, 2013).

A prohibited "proceeding 'for the enforcement' of the FDCA is one that seeks '[t]o give force or effect' and 'compel obedience to' the FDCA." FDA Amicus at 10

[14] "[T]he FDA's preemption determinations are significant," and are entitled to deference. *Horn v. Thoratec Corp.*, 376 F.3d 163, 170–71 (3d Cir. 2004) (citing express preemption provision); *accord Novartis Pharms. Corp. v. Leavitt*, 435 F.3d 344, 349 (D.C. Cir. 2006).

(citing Black's Law Dictionary (10th ed. 2014) (defining "to enforce")). Similarly, a "proceeding to 'restrain violations' of the FDCA seeks to prove and redress such violations." *Id*. Thus, "to give meaningful effect to Congress's mandate" in Section 337(a), the FDCA "precludes those private proceedings that rely on alleged violations of the FDCA as a necessary component of their cause of action and that seek to redress or restrain those FDCA violations." *Id.* at 10–11 (quoting § 337(a)).[15] In short, if the state-law claim depends on concepts or standards that exist "solely" because of the FDCA, it does not flow from a pre-existing state-law duty and is preempted. *Buckman*, 531 U.S. at 352–353; *see also Markland v. Insys Therapeutics, Inc*., 758 F. App'x 777, 779–80 (11th Cir. 2018) (per curiam).

The Complaints here attempt to do what Congress has prohibited: They dress up their allegations as state-law negligence *per se*, strict liability, warranty, and fraud claims, but these claims are really just attempts to privately enforce the FDCA's core prohibition on the manufacture and sale of purportedly "adulterated" drugs. 21 U.S.C. § 351 (defining "adulterated"); *id*. § 331(a)–(b) (prohibiting manufacture and sale of adulterated drugs). These claims are not based on conduct that *also* violates

[15] The Solicitor General similarly argued to the Supreme Court that Section 337(a) "precludes a private party from pursuing a claim that requires proof of a 'violation of FDCA requirements' and thus exists 'solely by virtue of the FDCA.'" Brief for the Federal Respondent ITC in Opposition at 12, *Amarin Pharma, Inc. v. ITC* (19–152) (Nov. 4, 2019), 2019 WL 5784708, at *12 (quoting *Buckman*, 531 U.S. at 352–353).

the FDCA, but depend on proving a violation of the FDCA *itself*, or proving a violation of a concept or standard that exists solely due to the FDCA. The claims depend on establishing that Defendants violated the FDCA by selling or manufacturing "adulterated drugs"—drugs that are, *inter alia*: non-compliant with cGMPs, *see id.* § 351(a)(1); different from their approved brand-name counterpart, *see id*. § 351(b); or mixed with a substance that reduces their quality, *see id*. § 351(d). Some claims also depend on establishing that Defendants violated the FDCA's requirements pertaining to the "duty of sameness" of generic drugs, *id*. § 355(j)(2)(A)(i)–(v), and drug labeling, *see id*. § 321(m). All such claims are preempted.

The Complaints' preempted claims fall into two general categories: (1) claims based on Defendants' alleged *conduct*; and (2) claims based on Defendants' alleged *misstatements* and *omissions*. The Complaints' negligence *per se* and design defect claims fall in the first category, alleging that Defendants manufactured a product that utilized methods that did not comply with the FDCA. *See infra* Part III.A.1; Charts at 7–9. The Complaints' breach of express warranty, fraudulent misstatement, negligent misstatement, and state consumer protection law claims are in the second category, alleging that Defendants represented that their products complied with the FDCA when they did not, or Defendants failed to affirmatively notify the public of

the drug's noncompliance with the FDCA.[16] *See infra* Part III.A.2; Charts at 7–9. Both depend on establishing a violation of the FDCA or, at the very least, on a factual basis that exists solely because of the FDCA, not state law.

1. The Complaints' Conduct-Based Claims Are Preempted Because They Depend on Proving Violations of the FDCA.

The Complaints' state-law claims relying on allegedly unlawful conduct are preempted because they depend on establishing a violation of the FDCA's sameness, cGMP manufacturing, and design requirements.

Negligence *Per Se*.[17] Negligence *per se* is the clearest example of a private attempt to enforce the FDCA masquerading as a state-law claim. Indeed, one of its core elements is proof that the defendant broke a law or regulation that was enacted for safety purposes. *See* Restatement (Third) of Torts: Liab. for Phys. & Emot. Harm § 14 (Am. Law Inst. 2010).

Here, the Complaints rely entirely on allegations that Defendants' conduct

[16] The Complaints also allege that Defendants failed to warn of the dangers of their products. *See, e.g.*, PIMC ¶ 443; MMMC ¶ 438. To the extent that claim is premised on a failure to warn FDA, it is on all fours with the "fraud-on-the-FDA" claim in *Buckman,* 531 U.S. at 348, and is preempted. *E.g.*, MMMC ¶ 438 ("Defendants failed to warn . . . [the] regulatory communities[] of the potential or actual contamination of the Valsartan with NDMA and NDEA, as soon as this was suspected or known."); *see also Mink v. Smith & Nephew, Inc*., 860 F.3d 1319, 1330 (11th Cir. 2017) (holding claim that defendant "failed to tell the FDA those things required by federal law" preempted under *Buckman*).

[17] ELMC Counts 17 ¶¶ 587–94 and 18 ¶¶ 595–602; PIMC Count 5 ¶¶ 466–480; MMMC Count 2 ¶¶ 406–413.

violated several requirements of the FDCA, including the sameness requirement and the cGMP provisions.[18] The disclaimer that, "Plaintiff is not seeking to enforce these federal provisions," PIMC ¶ 474, combined with a vague reference to "common law obligations," *id.* ¶ 469, does not salvage what is an overt attempt to enforce the FDCA. The Complaints have not identified *any* standard of care other than the standards supplied by the FDCA, and cannot make out a negligence *per se* claim without an underlying statutory violation. *See* Restatement (Third) of Torts: § 14 cmt. a; *see infra* Part V(C). To the extent the Complaints suggest that Defendants sold a "misbranded" or "new" drug because the label "omit[ted] ingredients," ELMC ¶¶ 171, 180, that too is simply an attempt to enforce the FDCA's sameness requirements.

Because noncompliance with the FDCA is a "critical element," the Complaints' negligence *per se* claims are preempted by Section 337(a).[19] Courts

[18] *E.g.*, ELMC ¶ 592 ("Each Defendant failed to comply with federal cGMPs and federal adulteration standards."); PIMC ¶ 467 ("Defendants violated federal statutes and regulations, including but not limited to the statutes cited herein."); MMMC ¶ 408 ("Each Defendant owed a duty to Plaintiffs and the Class to ensure that the VCDs it sold in the United States were therapeutically equivalent to brand Diovan and complied with cGMPs and were not adulterated or misbranded.").

[19] To the extent the Complaints' negligence and strict liability manufacturing defect claims rely on the FDCA to establish that a duty existed or the standard of care was breached, those claims are also preempted. *See, e.g.*, *Markland*, 758 F. App'x at 779–780. Plaintiffs' negligence and manufacturing defect claims, if allowed to proceed, must be limited to claims that derive from an independent state-law duty.

across the country have endorsed this view.[20]

Strict Liability – Defective Design.[21] The PIMC's defective design claim is an invalid private attempt to enforce the FDCA under the guise of state products liability law. It alleges without elaboration that Defendants' design failed to comply with the FDA-approved design and "caused consumers to suffer injuries." *E.g.*, PIMC ¶¶ 455–456. Putting aside the claim's facial deficiencies, *see infra* Part V(B)(1), the defective design claim is preempted. Charitably, it asserts that Defendants should have but did not comply with the FDA-approved design for valsartan. *See* PIMC ¶ 456. This dressed-up attempt by private parties to enforce compliance with the FDA-approved design is prohibited. *See* 21 U.S.C. § 337(a). As there is no independent state-law obligation for a drug manufacturer to comply with

[20] *See, e.g.*, *Dunbar v. Medtronic, Inc.*, No. 14-01529, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014) ("[A] negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages. Since the latter is not available as a result of § 337(a), the Court finds that the former is preempted as well."); *Leonard v. Medtronic, Inc.*, No. 1:10-cv-03787, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (same); *Sweezey v. C.R. Bard Inc.,* No. 3:19-cv-2172, 2020 WL 1237394, at *1 (N.D. Tex. Mar. 12, 2020) ("Texas courts . . . refuse to recognize a cause of action for negligence per se based on violations of the [FDCA] and FDA regulations.") (quoting *Monk v. Wyeth Pharm., Inc.,* No. 16-cv-1273, 2017 WL 2063008, at *8 (W.D. Tex. May 11, 2017)); *Hackett v. G.D. Searle & Co.,* 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002); *In re Bard IVC Filters Prods. Liab. Litig.*, No. 15-md-02641, 2018 WL 4356638, at *2 (D. Ariz. Sept. 12, 2018) (collecting at least ten cases).

[21] PIMC Count 3 ¶¶ 450–459.

an FDA-approved design for a generic drug, the claim is solely attributable to and dependent upon the FDCA and FDA's corresponding regulatory requirements.[22]

2. The Complaints' Representation-Based Claims Are Preempted Because They Depend on Proofs that Defendants Made False Statements About Their Compliance with the FDCA.

The Complaints' state-law claims relying on alleged misstatements and omissions by Defendants are preempted because they are mere variants on preempted fraud-on-the-FDA claims: They depend on violations of the FDCA's sameness, cGMP manufacturing, and labeling requirements.

Breach of Express Warranty, Fraudulent Misstatement, and Negligent Misstatement.[23] The Complaints allege that Defendants falsely warranted or represented that their VCDs complied with the FDCA when they did not, and that Defendants failed to affirmatively notify the public of their noncompliance with the FDCA.[24] These fraud-on-the-public claims alleging false statements of compliance

[22] To the extent the Complaints allege that the FDA-approved design itself was defective, that claim is preempted under the impossibility doctrine, since Defendants could not deviate from the FDA-approved design for valsartan. *See In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, No. 08-008, 2011 WL 5903623, at *6 (D.N.J. Nov. 21, 2011).

[23] ELMC Counts 1 ¶¶ 435–445; 2 ¶¶ 446–454; 7 ¶¶ 491–503; 8 ¶¶ 504–516; 9 ¶¶ 517–529; and 10 ¶¶ 530–542; PIMC Counts 8 ¶¶ 497–509 and 9 ¶¶ 510–519; MMMC Count 9 ¶¶ 477–490.

[24] In general, each of these causes of action require proof that Defendants made false representations about the products, either in the form of warranties, statements, or statements made false due to omission. *See* 63 Am. Jur. 2d *Prods. Liab.* §§ 631, 651 (express warranty); Restatement (Third) of Torts: Liab. for Econ. Harm § 9 (Am.

with the FDCA's requirements fail as mere variants of the fraud-on-the-FDA claims held preempted in *Buckman*. Such claims are entirely dependent on the FDCA.

By their own allegations, the Complaints' express warranty, fraudulent misstatement, and negligent misstatement theories require Plaintiffs to establish that the VCDs did not comply with the FDCA's sameness or cGMP requirements.[25] Noncompliance with the FDCA is thus a "critical element" of these claims. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013) (holding fraud by omission claim impliedly preempted because issue of FDCA compliance depended on questions of federal law that "rest within the enforcement authority of the FDA, not this Court." (internal quotation marks and citation omitted)); *see also Lewkut v.*

Law Inst. 2019) (fraudulent misstatements); *id.* § 5 (2019) (negligent misstatements). For purposes of this section, misrepresentation and omission are analyzed together as species of misstatements.

[25] As illustrative examples, the ELMC alleges that Defendants expressly warranted that their products "were compliant with cGMP and not adulterated or misbranded," ELMC ¶ 439, but Defendants breached that express warranty because the product "was not manufactured in compliance with cGMP and was adulterated or misbranded," *id.* ¶ 440. Similarly, the ELMC alleges that Defendants fraudulently misrepresented that their products were "therapeutically equivalent to their RLDs and/or complied with cGMPs and/or were not adulterated and/or misbranded," *id.* ¶ 493, when in fact the products "were not therapeutically equivalent to their RLDs and did not comply with cGMPs and/or were adulterated, misbranded, and/or unapproved," *id.* ¶ 494. And the PIMC alleges that Defendants "had a duty to disclose their dangerous and irresponsible practices of improperly designing, manufacturing, selling, marketing, and distributing drugs that did not have FDA approval[.]" PIMC ¶ 501.

Stryker Corp., 724 F. Supp. 2d 648, 659–60 (S.D. Tex. 2010) (finding claims based on alleged "adulterated" device preempted by § 337).

Representations as to compliance with the FDCA cannot serve as the basis for a claim under another law. *See Amarin v. ITC*, 923 F.3d 959, 969 (Fed. Cir. 2019) (holding false-advertising claim precluded because the claim "require[d] proving a violation of the FDCA itself"); *see also* FDA Amicus at 17–20 (citing *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010); *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 227–28 (3d Cir. 1990); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997)).

There is no difference between enforcing the FDCA directly (which is legally prohibited) and what the Complaints attempt to do here: hold Defendants liable for noncompliance with the FDCA based on purported warranties and representations about compliance with the FDCA (which is also legally prohibited). To hold otherwise would invite private enforcement by simply alleging that Defendants represented that they complied with the FDCA but did not. And because FDA-approved drug labels and labeling *always* represent compliance with the FDCA, every drug case could conceivably qualify for Plaintiffs' strategy here to avoid the impact of *Buckman* and its progeny.

State Consumer-Protection Laws.[26] The ELMC and PIMC assert claims under state consumer protection laws. The allegations are conclusory, so it is unclear what theory of liability those Complaints allege. Nevertheless, to the extent they intend to rely on Defendants' supposed misstatements concerning compliance with the FDCA to establish violations of state consumer-protection statutes, those claims are preempted for the same reasons as the express warranty and misstatement claims.[27]

B. The Court Should Dismiss or Abstain from Deciding the Complaints' Remaining Claims Because the FDA Has Primary Jurisdiction Over Those Claims.

Even though the Complaints' remaining claims do not expressly depend on establishing a violation of the FDCA, the Court should dismiss or stay Plaintiffs' claims for breach of implied warranty, strict liability failure-to-warn consumers, negligence, and manufacturing defect under the primary jurisdiction doctrine. The resolution of these claims is inextricably linked with pending FDA regulatory action, and the Court should abstain from intruding into FDA's expertise until the agency completes its investigation and related regulatory action.

The primary jurisdiction doctrine applies where claims "contain some issue

[26] ELMC Counts 11 ¶¶ 543–548 and 12 ¶¶ 549–554; PIMC Count 10 ¶¶ 520–579.

[27] For example, the PIMC alleges rather broadly that Defendants violated state consumer protection statutes when they, *inter alia*, "falsely marketed the drugs taken by Plaintiffs as generic versions and bio-equivalents of Diovan." PIMC ¶ 521.

within the special competence of an administrative agency." *Reiter v. Cooper*, 507 U.S. 258, 268 (1993). It "calls for judicial abstention in cases where protection of the integrity of a regulatory scheme dictates primary resort to the agency which administers the scheme." *Global Naps, Inc. v. Bell Atl.-N.J., Inc.*, 287 F. Supp. 2d 532, 549 (D.N.J. 2003) (quoting *Cheyney State Coll. Faculty v. Hufstedler*, 703 F.2d 732, 736 (3d Cir. 1983)). In determining its applicability, courts consider four factors: (1) whether the question "is within the conventional experience of judges" or instead "involves technical or policy considerations within the agency's particular field of expertise"; (2) whether the question "is particularly within the agency's discretion"; (3) whether there exists "a substantial danger of inconsistent rulings"; and (4) whether a "prior application to the agency has been made." *Raritan Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011) (quoting *Global Naps*, 287 F. Supp. 2d at 549). All four factors favor abstention here.

First, though certain of the Complaints' breach of implied warranty, failure-to-warn, and negligence claims purport to be based on traditional state-law duties, the Complaints frame these claims in terms of technical drug manufacturing and safety issues. The Complaints' allegations require investigation into whether Defendants' VCDs are bioequivalent in their pharmacokinetic profiles to the brand or reference listed drugs ("RLDs"), should be "A/B rated" and listed in FDA's "Orange Book," are manufactured in accordance with cGMPs, meet FDA's safety,

quality, purity, identity, and strength standards, and conform to FDA-approved labeling.[28]

These are matters outside the Court's conventional expertise and squarely within FDA's specialized expertise and legislative mandate. *See* 21 U.S.C. §§ 321, 371-72, 375, 393(a). FDA "has primary jurisdiction to make the initial determination on issues within its statutory mandate[.]" 21 C.F.R. § 10.25(b). "[T]he possibility that a conflict may arise if a court were to decide a matter inextricably intertwined with an intensive regulatory scheme requires judicial abstention in such cases." *Torres-Hernandez v. CVT Prepaid Sols., Inc.*, No. 3:08-cv-1057, 2008 WL 5381227, at *3 (D.N.J. Dec. 17, 2008) (citing *Cheyney State Coll.*, 703 F.2d at 736; *MCI Commc'n Corp. v. AT&T Co.*, 496 F.2d 214, 220 (3d Cir. 1974)).

Second, the questions raised by the Complaints also lie squarely within FDA's discretion. Plaintiffs concede, as they must, that FDA is primarily responsible for many discretionary matters underlying Plaintiffs' allegations, including the generic drug approval framework, maintaining the "Orange Book," the promulgation and enforcement of cGMPs, the regulation governing the "quality control unit," the interim safety limit for NDMA, the regulation governing sampling and testing of in-

[28] PIMC ¶¶ 193, 210, 222, 224–235, 266-347; ELMC ¶¶ 168–174, 179–187, 201, 224–302, 352–354, 376; MMMC ¶¶ 130–126, 141–150, 154–155, 164, 186–265, 318–320, 342.

process materials and drug products, warning letters, inspections, recalls, and labeling, and the preparation and content of medication guides.[29] Each discretionary subject area calls for application of the primary jurisdiction doctrine to permit FDA to address these important issues and carry out its responsibilities, which are unique among domestic regulatory agencies.

Further supporting primary jurisdiction abstention in this MDL is the role of ongoing recalls in the Complaints. FDA has discretion with respect to the commencement, classification, conduct, and termination of recalls. *See* 21 C.F.R. §§ 7.40–7.59. The Complaints rest on allegations pertaining to the recall of the Manufacturer Defendants' VCDs, and the allegation that these recalls are just the "tip of the iceberg" with further recalls yet to occur. *E.g.,* PIMC ¶¶ 8, 169–185, 391; ELMC ¶¶ 2, 346–350, 405; MMMC ¶¶ 313–316, 381. The primary jurisdiction doctrine strongly militates in favor of the Court's abstention, yielding to the discretion entrusted to FDA by Congress to investigate and determine outcomes on key issues, including those enumerated above, which are predominantly within its jurisdiction.

Third, the Complaints' remaining claims give rise to a substantial danger of inconsistent rulings. The Complaints seek to adjudicate whether any of Defendants'

[29] *See, e.g.*, PIMC ¶¶ 170, 186, 193, 219–222, 224–226, 232, 235, 278, 289, 295, 320, 334, 338, 346–347.

generic VCDs contain NDMA or NDEA and whether Defendants have complied with cGMPs and numerous other statutory and regulatory requirements under FDA's primary authority, praying for declaratory, injunctive and monetary relief as to Plaintiffs and their putative classes. At the same time, according to the Complaints' allegations, FDA remains actively engaged in ongoing regulatory action with additional action possible in the future.[30] There is an unavoidable risk that this Court may be asked to enter interim or permanent relief, commence discovery, make dispositive rulings, or otherwise take consequential action that may contradict FDA's action with respect to Defendants' VCDs. This places the Court at risk of steering a course materially at odds with FDA's own actions. Because the issues before this Court are "factually and legally intertwined" with those "pending resolution" before FDA, abstention on primary jurisdiction grounds is fully appropriate. *Iowa Network Servs. v. AT&T Corp.*, No. 3:14-cv-3439, 2019 WL 4861438, at *6 (D.N.J. Oct. 2, 2019) (citation omitted)).

Fourth, FDA has an ongoing, multidisciplinary investigation underway to evaluate and address potential impurities in valsartan.[31] *See supra* n.9. Where an issue before the Court is "presently pending" before FDA, that weighs in favor of

[30] *See, e.g.*, PIMC ¶ 182; ELMC ¶¶ 5, 354; MMMC ¶ 316.

[31] *See, e.g.,* PIMC ¶¶ 8, 169–185, 391; ELMC ¶¶ 2, 346–350, 405; MMMC ¶¶ 313–316, 381.

abstention. *See Gisvold v. Merck & Co.*, 62 F. Supp. 3d 1198, 1204 (S.D. Cal. 2014). The Court should avoid unnecessarily stepping into FDA's shoes.

Accordingly, because "all primary jurisdiction factors are present in this action," dismissal or a stay is appropriate until FDA completes all pending and future proceedings and actions addressing the same subject matters as are involved in these cases and this MDL. *Iowa Network Servs.*, 2019 WL 4861438, at *6.

IV. THE COMMON LAW CLAIMS OF NEW JERSEY AND SIMILARLY-SITUATED PLAINTIFFS ARE SUBSUMED BY STATE PRODUCT LIABILITY STATUTES.

Many Plaintiffs' state common law claims are subsumed under their applicable states' product liability acts ("PLAs"). The New Jersey Products Liability Act ("NJPLA"), for example, subsumes "*any cause of action* 'for harm caused by a product, irrespective of the theory of the underlying claim,'" except for breach of express warranty.[32] *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 596–598 (D.N.J. 2015) (emphasis added) (quoting N.J.S.A. § 2A:58C-1(b)(3)). The NJPLA supplies "one unified, statutorily defined theory of recovery for harm caused

[32] Likewise, state consumer protection claims, including statutory claims, arising out of alleged product defects are subsumed by the NJPLA. *See Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 819 (D.N.J. 2019) (collecting cases holding NJPLA subsumes claims for statutory consumer fraud, breach of warranty, negligence and fraud-based claims arising out of alleged deceptively designed medical device); *Cole v. NIBCO, Inc.*, No. 3:13-cv-07871, 2015 WL 2414740, at *5–7 (D.N.J. May 20, 2015) (holding consumer fraud, tort, breach of warranty, and unjust enrichment claims subsumed by NJPLA and Tennessee PLA).

by a product[.]" *In re Lead Paint Litig.*, 924 A.2d 484, 503 (N.J. 2007). Except for breach of express warranty, "all claims for harm caused by a product under New Jersey law, *regardless of the theory underlying the claim*, are governed by the [NJPLA]," and the NJPLA "is the *exclusive remedy* for such actions and other claims are subsumed within the statutory cause of action." *Calender v. NVR Inc.*, 548 F. App'x 761, 764 (3d Cir. 2013) (emphases added).

Many of the states represented in this MDL have similar PLAs that subsume common law claims. The Court should dismiss all state common law claims subsumed by state PLAs, a complete list of which is set forth in the Charts at 16–19.

A. The NJPLA and Similar Statutes Subsume the PIMC and MMMC's Claims.

All state law claims (except for breach of express warranty) brought by New Jersey and MMMC Plaintiffs are subsumed by the NJPLA and should be dismissed. The PIMC's claims are subsumed because they emanate from physical harm. *See Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 822–23 (D.N.J. 2019). Medical monitoring claims, like those set forth in the MMMC, are also subsumed. *See Sinclair v. Merck & Co., Inc.*, 948 A. 2d 587, 593–595 (N.J. 2008). Other states' statutes have a similar effect. *See* Charts at 16–19.

B. The NJPLA Subsumes the ELMC's Claims.

The NJPLA also subsumes any common law claims, including economic loss claims, where "the heart of [ ] matter is the *potential* for [physical] harm [to

plaintiffs]" and any alleged economic damage arises from this potential danger to plaintiffs' health.[33] *Levinson v. Johnson & Johnson Consumer Cos., Inc.*, No. 09-cv-3317, 2010 WL 421091 (D.N.J. Feb. 1, 2010) (emphasis added), *reconsidered on other grounds* 2010 WL 3024847 (D.N.J. Aug. 2, 2010) (dismissing complaint); *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 706 (D.N.J. 2011). Applying this principle, New Jersey courts have held the NJPLA subsumes economic loss claims predicated on allegations that carcinogenic impurities rendered a product "useless." *See Crouch v. Johnson & Johnson Consumer Cos., Inc.*, No. 09-cv-2905, 2010 WL 1530152, at *7 (D.N.J. Apr. 15, 2010) (holding claims for economic loss arising out of allegedly contaminated bath products were subsumed); *Boyd v. Johnson & Johnson Consumer Cos., Inc.*, No. 09-cv-3135, 2010 WL 2265317 (D.N.J. May 31, 2010) (same) *reconsidered on other grounds* 2010 WL 3024845, at *6 (D.N.J. Aug. 2, 2010) (dismissing complaint).

"[A]rticulating a claim in terms of pure economic harm" does not "convert[] the underlying defective product claim into an independent and unrelated [issue]" and "cannot be used to obviate the [NJPLA]." *Crouch*, 2010 WL 1530152, at *7.

[33] Although the "potential for harm" may bring the ELMC's claims within the analytical purview of the NJPLA, it is not sufficient to allege any *actual*, non-speculative Article III economic injury. *See supra* Part II.A; *Crouch*, 2010 WL 1530152, at *4 (dismissing economic loss claims involving certain chemicals for lack of standing because "any potential injury is too remote, hypothetical and/or conjectural . . .").

The same is true here; the "heart" of the ELMC is the "potential" for harm posed by VCDs allegedly containing nitrosamine impurities. *See* ELMC ¶¶ 170, 372; MMMC ¶¶ 1, 293. The result is the same for other states' product liability statutes. *See* Charts at 16–19.

V. THE COMPLAINTS' INDIVIDUAL CLAIMS SHOULD BE DISMISSED UNDER RULE 12(B)(6) BASED ON CLAIM-SPECIFIC PLEADING DEFECTS.

The preceding sections address deficiencies in the Complaints that apply across multiple claims or Complaints. Most or all of the Complaints' 32 individual claims also contain claim-specific legal and facial deficiencies further supporting their dismissal. These defects are too numerous to catalog in any single motion, but the Manufacturing Defendants will address key deficiencies in each set of claims warranting their dismissal.

A. The Complaints' Fraud Claims Should be Dismissed.

All three Complaints contain variants of fraud claims based on Defendants' purported misrepresentation of the properties of their VCDs. These claims are all defective because they fail to allege fraud with sufficient particularity and fail to allege scienter or knowledge.

1. The Complaints Do Not Satisfy the Heightened Pleading Requirement for Fraud.

The Complaints fail to allege *any* factual basis for their fraud claims, much less particularized facts satisfying the "heightened specificity requirements" for

fraud under Rule 9(b). *MDNet, Inc. v. Parmacia Corp.*, 147 F. App'x 239, 245 (3d Cir. 2005). To meet Rule 9(b)'s requirements, plaintiffs must provide factual allegations detailing the "who, what, when, where, and how" of a fraud claim. *Rapid Models & Prototypes, Inc. v. Innovated Sols.*, 71 F. Supp. 3d 492, 504 (D.N.J. 2014). Moreover, a fraud claim will be dismissed where a "Plaintiff lumps all [defendants] together as having engaged in wrongful conduct without specifying which defendant was responsible for which actions." *Snyder v. Dietz & Watson, Inc.*, 837 F. Supp. 2d 428, 450 (D.N.J. 2011).

Here, the Complaints are devoid of specific facts alleging how any consumer was defrauded by any Defendant because of the alleged nitrosamine impurities in VCDs. The Complaints do not allege any misstatements on the part of any individual or Defendant with any specificity, *i.e.*, who, what, where, and when. And the Complaints routinely lump all Defendants together without pleading particular facts regarding the alleged misconduct of each. Accordingly, the Complaints' fraud claims should be dismissed in their entirety.

2. The Complaints Do Not Sufficiently Plead that Defendants Knew Any Representations Were False.

The Complaints also fail to satisfy the element of knowledge or scienter to state a claim for fraud. Plaintiffs allege that Defendants knew or "should have

known" of their putative false representations.[34] But that is not the standard for fraud. Though the scienter or knowledge requirement is expressed somewhat differently among states, all states require actual knowledge, or, in some instances, recklessness. *See* Charts at 20–21, 22. The Complaints cannot satisfy any version of this element.

The Complaints do not allege, beyond conclusory averments, that Defendants knew their VCDs contained nitrosamines. For example, the Complaints allege that "there are indications that Defendants had actual knowledge" and that "Defendants knowingly . . . introduced adulterated and/or misbranded VCDs containing dangerous amounts of nitrosamines into the U.S. market." *See, e.g.*, ELMC ¶¶ 348, 353; PIMC ¶¶ 196, 200, 505; MMMC ¶¶ 306, 310–311. These conclusory allegations are insufficient to establish scienter to support a fraud claim.

Indeed, the Complaints' allegations concede Defendants' ***lack*** of knowledge. The Complaints devote many paragraphs to Defendants' alleged inappropriate manufacturing practices, yet in the same breath also concede Defendants' lack of knowledge, asserting that had Defendants adhered to FDA's guidelines, they "*would have found* the NDMA and NDEA contamination almost immediately." *See*, *e.g.*, ELMC ¶ 344; PIMC ¶ 192; MMMC ¶ 302 (emphasis added). This use of the past modal tense ("would have found") signifies that Defendants *did not in fact* learn of

[34] *See* ELMC ¶¶ 496–497; PIMC ¶¶ 397, 419, 425–426; MMMC ¶¶ 5, 305.

the alleged contamination, indicating their lack of knowledge. Nor do the Complaints allege facts establishing an intent to deceive or facts surrounding the alleged fraud to support recklessness in those states applying a recklessness standard. *See* Charts at 22.

Thus, having failed to allege facts supporting the necessary scienter element, the fraud claims asserted in each MC should be dismissed. *Danon v. Vanguard Group, Inc.*, 686 F. App'x 101, 103 (3d Cir. 2017) (stating that "[b]ecause knowledge is a necessary element of [plaintiff's] claim, failing to plead knowledge adequately was sufficient to warrant dismissal").

B. The PIMC and MMMC Fail to Allege Design Defect and Failure-to-Warn Product Liability Claims.

The Complaints assert products liability claims, alleging that the VCDs (1) were defectively designed and (2) lacked adequate warnings. Though each of these allegations and claims must be evaluated pursuant to each governing state's law, certain pleading deficiencies cut to the core and render these claims uniformly inadequate under *any* state's law. Further, some states categorically reject strict liability in the products liability context for design defect and failure-to-warn claims. Dismissing those claims now will greatly streamline these cases.[35]

[35]Additionally, to the extent any of Plaintiffs' product liability claims are premised on the notion that Defendants had a state-law duty to alter their labeling, *see* 21 C.F.R. § 202.1(l)(2) (defining "labeling"), those claims are preempted pursuant to *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). To the extent any of Plaintiffs' claims

1. The PIMC Inadequately Alleges a Design Defect Claim.

The PIMC asserts a strict liability design defect claim but contains only conclusory allegations that parrot the elements of the claim.[36] A product is defectively designed if it is unreasonably dangerous for its intended use, despite being manufactured as intended. Restatement (Second) of Torts, § 402A (1965). A design is deemed unreasonably dangerous if the risk of harm outweighs the benefits of the product. *Id.*; *see also* Restatement (Third) of Torts: Prod. Liab. § 6 (1998) ("A prescription drug . . . is not reasonably safe due to defective design if the foreseeable risks of harm . . . are sufficiently great in relation to its foreseeable therapeutic benefit[.]"). The PIMC does not plead facts establishing these elements.

At the outset, it is unclear how the PIMC asserts a defective design claim at all. Plaintiffs do not allege that Defendants' *designed* their VCDs to contain nitrosamines. To the contrary, they assert this condition occurred as a result of deficiencies in Defendants' manufacturing practices that resulted in the VCDs containing an unintended byproduct in the form of nitrosamines. *See, e.g.*, PIMC ¶¶ 10–11, 266–345. Thus, Plaintiffs' design defect claim fails at the most basic level: There is no plausible allegation of a defective design.

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are premised on the notion that Defendants were required under state law to change the design of the VCDs or the process used to make them, those claims are preempted under *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *see supra* n.26.

[36] *See* PIMC ¶¶ 450–459.

Even if some design defect were at issue, the PIMC contains no factual allegations whatsoever as to the other elements of a defective design claim, and therefore fails to allege a plausible claim under *any* state's law. The PIMC simply recites the elements and alleges the VCDs were "defectively designed because the design was unsafe for the purposes intended by Defendant," PIMC ¶ 453, and "foreseeable risks of harm could have been reduced or avoided by adopting a reasonable alternative design, as originally approved by the FDA," *id.* ¶ 456. It concludes by asserting, without elaboration, that "Defendants did not adopt a design that would have rendered these drugs reasonably safe." *Id*.

The PIMC does not identify any aspect of the design as defective, nor does it specify any deviation from the "FDA-approved" design. *See Bell v. Boehringer Ingelheim Pharms., Inc*., No. 17-1153, 2018 WL 928237, at *5 (W.D. Pa. Feb. 15, 2018) ("The complaint does not plead any facts, however, about why this design is defective. [Plaintiff] conclusorily alleged that 'several alternative safer products' exist but did not identify those products or explain why they are safer."). The PIMC does not even attempt to weigh the therapeutic benefits of the VCDs against the purported harms. *See Becker v. Smith & Nephew, Inc*., No. 14-5452, 2015 WL 268857, at *4 (D.N.J. Jan. 20, 2015) (same failure resulting in dismissal). These allegations are insufficient to support a strict liability design defect claim in the states

where such a claim is legally cognizable.[37] *See, e.g.*, *Glick v. Leatt Corp.*, No. 4:17-cv-00291, 2018 WL 9439696, at *2 (S.D. Iowa May 3, 2018), *aff'd sub nom. Glick v. W. Power Sports, Inc.*, 944 F.3d 714 (8th Cir. 2019) (dismissing design defect claim that did nothing more than recite elements as bare "legal conclusions, unsupported by any other facts"); *Forslund v. Stryker Corp.*, No. 09-2134, 2010 WL 3905854, at *2 (D. Minn. Sept. 30, 2010) (same); *Bosch v. Bayer Healthcare Pharm., Inc.*, 13 F. Supp. 3d 730, 743 (W.D. Ky. 2014) (same); *Thornton v. AstraZeneca Pharm. LP*, No. 1:17-cv-652, 2017 WL 2255776, at *4 (N.D. Ga. May 15, 2017) (same).

2. The PIMC and MMMC Inadequately Allege Failure-to-Warn Claims.

The PIMC and MMMC also inadequately allege failure-to-warn claims based on Defendants' claimed failure to warn of the dangers associated with the recalled VCDs, under both strict liability and negligence theories.[38] Absent from both Complaints is the critical element that Defendants knew or had reason to know that

[37] Many states do not recognize strict liability design defect claims at all. *See* Charts at 23–27.

[38] *See* PIMC Count 2 ¶¶ 438–449 and MMMC Count 5 ¶¶ 437–442 (strict liability claims); PIMC Count 9 ¶¶ 510–519 and MMMC Count 1 ¶¶ 394–405 (negligence claims). As to negligence, those claims can further be divided into negligent misrepresentation and negligent omission theories of liability. For convenience, this submission refers to negligent misstatements. As to strict liability, certain states do not recognize strict liability failure-to-warn claims at all. *See* Charts at 28.

the VCDs contained the nitrosamine impurity. A warning is inadequate "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings . . . and the omission of the instructions or warnings renders the product not reasonably safe." Restatement (Third) of Torts: Prod. Liab. § 2 (1998); *see also* Restatement (Third) of Torts: Prod. Liab. § 6 (1998).

But a defendant can only warn of a risk about which it knows or has reason to know. *See* Restatement (Second) of Torts § 402A cmt. j (1965) (seller must warn "*if he has knowledge*, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger") (emphasis added). In a case like this one, therefore, a plaintiff must allege that the seller knew or should have known of the presence of—and the foreseeable harm which may be caused by—the impurity. Restatement (Third) of Torts § 6 cmt. g (1998); *accord Anderson v. Owens-Corning Fiberglas Corp*., 53 Cal. 3d 987, 1000 (1991) ("majority of jurisdictions" agree that "knowledge or knowability is a component of strict liability for failure to warn").

The PIMC and MMMC do not allege any facts suggesting that Defendants either knew or should have known about the alleged impurity in their VCDs, that the presence of the impurity was foreseeable, or that the impurity was present in

quantities sufficient to cause harm.[39] Thus, failure-to-warn claims are not sustainable on the face of the Complaints.

C. Plaintiffs' Negligence *Per Se* Claims Must be Dismissed.

Each of the Complaints avers negligence *per se*.[40] These claims are inadequately pleaded or are not cognizable under individual states' laws.

1. The ELMC and MMMC Do Not State Claims for Negligence *Per Se*.

The ELMC and MMMC fail to allege that Plaintiffs are within a class of individuals any statute or regulation was designed to protect—a required element of negligence *per se* in many states. *See* Charts at 29–30. Putting aside that private efforts to enforce the FDCA under the guise of negligence *per se* are preempted, *see infra* Part III.A.1, the ELMC and MMMC are devoid of any allegation that the statutes, regulations, and cGMP they claim were violated were intended to protect Plaintiffs. Accordingly, the negligence *per se* claims should be dismissed as to all states requiring this element, listed in the Charts at 29–30.

2. The Complaints' Negligence *Per Se* Claims are Not Cognizable Under the Law of Multiple States.

A number of states do not recognize negligence *per se* as a separate cause of action, finding a violation of a statute is either deemed simply evidence of

[39] *See* PIMC ¶¶ 438–449, 510–519; MMMC ¶¶ 437–442, 394–405.

[40] *See* PIMC Count 5; ELMC Counts 17 and 18; MMMC Count 2.

negligence, or they impose other state-specific requirements on negligence *per se* claims. The Manufacturing Defendants have identified in the Charts at 31 the states disallowing the Complaints' negligence *per se* claims on state-specific grounds; these claims should be dismissed as to each such state.

D. The Complaints' Negligence Claims Should Be Dismissed.

Negligence is a highly variable cause of action whose requirements vary from state to state, yet Plaintiffs pursue negligence claims in a broad brush manner in each of the Complaints.[41] Those claims fall short under the law of multiple states. Most notably, many states' economic loss rules preclude recovery of damages for negligence unless a plaintiff has pled physical injury or property damage. The ELMC and MMMC do not allege current physical injury or property damage resulting from Defendants' VCDs. Therefore, the negligence claims in those Complaints should be dismissed as to those states listed in the Charts at 32–34.

E. The Complaints Do Not State Cognizable Breach of Implied and Express Warranty Claims.

Each of the Complaints assert claims for breach of express and implied warranties. The implied warranty claims allege lack of merchantability—*i.e.*, fitness for the VCDs' ordinary purposes.[42] Plaintiffs also allege two types of express

[41] *See* PIMC Count 4 ¶¶ 460–465; ELMC Counts 15 ¶¶ 567–576 and 16 ¶¶ 577–586; and MMMC Count 1 ¶¶ 394–405.

[42] *See, e.g.*, ELMC ¶¶ 472–473; PIMC ¶¶ 492; MMMC ¶¶ 326. Although Plaintiffs do not explicitly allege separate claims for breach of any implied warranty of fitness

warranties emanating from Defendants label and non-label representations. First, Plaintiffs allege Defendants breached the "express warranty of sameness" contained within the VCDs' labels, which Plaintiffs imply guaranteed that the valsartan products would be bioequivalent and therapeutically equivalent to their RLDs and have the same "quality," safety, efficacy, and strength.[43] Second, Plaintiffs also claim that all Defendants breached their express warranties created through their websites or other marketing materials.

1. State Law Privity Requirements Compel Dismissal of Plaintiffs' Express and Implied Warranty Claims.

Numerous states require privity of contract for breach of express warranty, implied warranty, or both as set forth in the Charts at 35–38.[44] Because the ELMC and MMMC have failed to allege privity between Plaintiffs and the Manufacturer

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for a particular purpose ("FPP"), "if the particular purpose . . . coincides with [the] general functional use, the implied [FPP warranty] merges with the implied warranty of merchantability." *Cartillar v. Turbine Conversions, Ltd.*, 187 F.3d 858, 861 n.5 (8th Cir. 1999). Moreover, any claim for an FPP warranty fails because manufacturers were unaware of any Plaintiff's particular purpose in taking a VCD beyond the ordinary purposes for which VCDs were prescribed and used, and the Plaintiffs' Complaints articulate no such individualized purpose. *See Doe v. Solvay Pharmaceuticals, Inc.*, 350 F. Supp. 2d 257, 265 (D. Me. 2004).

[43] *E.g.,* ELMC ¶¶ 363–364, 366–367, 369, 437, 448; PIMC ¶¶ 482–483; MMMC ¶¶ 322–323.

[44] Consumers lack privity with a manufacturer where they did not purchase the product directly from that manufacturer. *See Avram v. Samsung Electronics Am., Inc*., Nos. 2:11-6973, 2:12-976, 2013 WL 3654090, at *11 (D.N.J. July 11, 2013).

Defendants, these claims should be dismissed as to the states listed in the Charts at 35–38.[45]

2. The Implied Warranty Claims in the ELMC and MMMC Fail for Lack of Injury or Loss of Functionality.

The ELMC and MMMC do not allege that Plaintiffs have suffered any present physical harm or that they failed to receive the same therapeutic value from their VCDs as the RLDs. Plaintiffs must show how an alleged defect impaired the product's functionality or caused actual injury, not merely that a defect or impurity existed, to state a claim for breach of implied warranty. *See Hoffman v. Nutraceutical Corp.*, No. 12-5803, 2013 WL 2650611, at *4 (D.N.J. June 10, 2013) (dismissing implied warranty claim for lead-containing supplement because plaintiff failed to plead or demonstrate injury); *Hammer v. Vital Pharms., Inc.*, No. 11-4124, 2012 WL 1018842, at *12 (D.N.J. Mar. 26, 2012) (dismissing implied warranty claims where plaintiff merely claimed supplement contained synthetic components); *Bowman v. Ram Med., Inc*. No. 10-cv-4403, 2012 WL 1964452, at *5 (D.N.J. May 31, 2012) (finding that plaintiff's allegation of receiving a counterfeit mesh implant could not alone sustain claims of breach of an implied warranty); *Crozier v. Johnson & Johnson Consumer Cos., Inc*., 901 F. Supp. 2d 494, 508–509 (D.N.J. 2012)

[45] At least four of the PIMC states at issue also require privity in the personal injury context. *See* Charts at 35–38.

(dismissing claims where plaintiff did not allege impaired functionality or physical injury).

Because the ELMC and MMMC are devoid of allegations of impaired functionality or actual injury, the Court should dismiss all implied warranty claims.

3. All Express Warranty Claims Fail Under State Law.

The Complaints also fail to allege the requisite elements of a claim for breach of express warranty. To state a claim for breach of express warranty under New Jersey law, a plaintiff must allege three elements: (1) Defendant made an affirmation, promise or description about the product; (2) that became part of the basis of the bargain; and (3) the product ultimately did not conform to the affirmation or description." *Snyder v. Farnam Co., Inc.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011). The Complaints are deficient and do not contain these averments.

a. The Complaints Fail to Allege That Any Warranty Formed the Basis for Any Bargain.

Although all of the Complaints allege various purported express warranties, they do not allege what—if anything—any plaintiff saw or read *before* filling a valsartan prescription that constituted a warranty upon which he or she relied.[46] At a minimum, a breach of express warranty claim requires the alleged warranty to form the basis of the bargain by alleging they "bought a product *based on* a particular

[46] *See, e.g.*, PIMC ¶¶ 481–490 (never stating Plaintiffs saw, read, or understood the express warranties at issue prior to their purchases).

promise[.]" *Mladenov v. Wegmans Food Markets, Inc.*, 124 F. Supp. 3d 360, 378 (D.N.J. 2015) (emphasis added). This requires Plaintiffs to demonstrate they first "saw" the warranty and "purchased [the products] as a result." *Id.*; *see also Walters v. Carson*, No. 11-6545, 2012 WL 6595732, at *3 (D.N.J. Dec. 17, 2012) (Kugler, J.). Because the Complaints do not contain any such allegations, their express warranty claims fail and should be dismissed.[47]

b. The Complaints Do Not Identify Specific Language, Sources, and Effective Time Periods to Establish Express Warranties.

New Jersey and other states require a plaintiff to identify (1) the specific language or guarantee of an express warranty and (2) the source of a warranty. *See Arlandson*, 792 F. Supp. 2d at 707; *In re Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, 588 Fed. App'x 171, 175 (3d Cir. 2014) (applying New Jersey law); *Fishman v. Gen. Elec. Co.*, No. 2:12-cv-00585, 2013 WL 1845615, at * 5 (D.N.J. Apr. 30, 2013). Many of Plaintiffs' warranty claims only identify one of the elements, while some identify neither. *See* Charts at 42.[48] Claims based on the warranties identified as deficient in the Charts at 42 should be dismissed.

[47] All jurisdictions adopting the UCC contain a "basis of the bargain" requirement. *See* Charts at 39–41.

[48] Stating an express warranty's language and source are pleading requirements under *Twombly, see Simmons v. Stryker Corp.*, No. 08-3451, 2008 WL 4936982 at *1–2 (D.N.J. Nov. 17, 2008), as opposed to a substantive requirement of state law.

c. Representations About Safety or Efficacy of VCDs Do Not Create Express Warranties.

Because federal law requires the labeling of valsartan products to disclose risks, contraindications, and side effects, their labels cannot create legally enforceable warranties about the safety or efficacy of those drugs. *See Avandia*, 588 Fed. App'x. at 175. Federal courts interpreting the law of several states, "have refused to find the words 'safe and effective' to create an express warranty in the absence" of a guarantee that the drug "was free from all harmful side effects or was absolutely harmless." *Id.* at 176. Here, the PIMC similarly relies on the premise that Defendants guaranteed valsartan was "safe and effective." *See* PIMC ¶¶ 482–483. Thus, the PIMC's express warranty allegations should be dismissed.

4. State Law Pre-Suit Notice Requirements Compel Dismissal of the Complaints' Express and Implied Warranty Claims.

Because the Complaints do not plead pre-litigation notice, the implied and express warranty claims of Plaintiffs from jurisdictions that require such notice must be dismissed. *See* Charts at 43–48.

5. The Complaints' Magnuson-Moss Warranty Act Claims Fail.

The Magnuson-Moss Warranty Act ("MMWA") is inapplicable to any alleged express or implied warranty claims concerning the labeling of valsartan products because federal law controls the content of a generic drug's label. *See* 15 U.S.C. § 2311(d) (stating MMWA does not apply to "any written warranty the making or content of which is otherwise governed by Federal law"); *Dopico v. IMS Trading*

Corp., No. 14-cv-1874, 2018 WL 4489677, at *6 (D.N.J. Sept. 18, 2018) (holding MMWA is inapplicable to labeling of products regulated by the FDA). Even if FDA regulations did not foreclose Plaintiffs' MMWA claims, they fail for the same reasons that Plaintiffs' state implied and express warranty claims fail. *See, e.g.*, *Johansson v. Cent. Garden & Pet Co*., 804 F. Supp. 2d 257, 265 (D.N.J. 2011) (dismissing MMWA claim where underlying state claim was dismissed). They also fail because Plaintiffs do not allege they afforded Defendants "a reasonable opportunity to cure such failure to comply." 15 U.S.C. § 2310(e). Therefore, all of Plaintiffs' MMWA claims should be dismissed.

F. The ELMC's Unjust Enrichment Claims Are Inadequately Pleaded.

The ELMC's allegations of unjust enrichment consist of nothing more than a recitation of the elements of an unjust enrichment claim. Likewise, they are not directed to any particular Defendants, rendering it impossible to tell which Defendant was supposedly enriched unjustly and by whom. *See D'Addario*, 2020 WL 3546750, at *6 (quoting *Sheeran v. Blyth Shipholding S.A*., No. 14-5482, 2015 WL 9048979, at *3 (D.N.J. Dec. 16, 2015)) ("'[G]roup pleading' does not satisfy Rule 8[ ] because it does not place Defendants on notice of the claims against each of them[.]'"). Though unjust enrichment law varies considerably by state, these bare assertions fail to state the most basic facts underlying such a claim. *See, e.g.*, *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 544, 555) ("[T]he pleading standard

Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. . . . A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'").

Beyond these basic pleading deficiencies, certain states require that a plaintiff expressly plead the absence of an adequate remedy at law. *See* Charts at 49. The ELMC contains no such allegations, nor does it plead unjust enrichment in the alternative.

The claims likewise fail because they hinge on the same allegations of wrongful conduct as the ELMC's eighteen other causes of action. *See, e.g.*, *Bourbia v. S.C. Johnson & Son, Inc.*, 375 F. Supp. 3d 454, 466 (S.D.N.Y. 2019) (although New York allows plaintiffs to plead unjust enrichment in the alternative, where it "is duplicative of other causes of action," *i.e.*, it "relies on the same conduct that forms the basis of [ ] other claims[,]" "it should be dismissed"); *Jovine v. Abbott Labs., Inc.*, 795 F. Supp. 2d 1331, 1342–1343 (S.D. Fla. 2011) (noting that if a plaintiff seeks recovery under unjust enrichment for the exact same wrongful conduct that form the basis of her other claims, the unjust enrichment claim will be dismissed); *Wahlcometroflex, Inc. v. Baldwin*, 991 A.2d 44, 49–50 (Me. 2010) (applying Delaware law and dismissing unjust enrichment claim where it was based on the same factual allegations as plaintiff's breach of fiduciary duty claim). Not only are

the unjust enrichment claims duplicative, but the other causes of action also aptly demonstrate the plethora of adequate legal remedies available to Plaintiffs. *See, e.g.*, *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 16 (1st Cir. 2017) (applying Massachusetts law and dismissing plaintiff's unjust enrichment claim even though plaintiff's other legal claims were dismissed, because "[i]t is the availability of a remedy at law, *not the viability of that remedy*, that prohibits a claim for unjust enrichment") (emphasis supplied); *Indiana ex rel. Zoeller v. Pastrick*, 696 F. Supp. 2d 970, 999 n.7 (N.D. Ind. 2010) (noting that "[u]nder Indiana law, equitable principles such as unjust enrichment will not apply where there exists a remedy at law") (citation omitted); *Duffy v. Charles Schwab & Co., Inc.*, 123 F. Supp. 2d 802, 814 (D.N.J. 2000) (recognizing that "[r]estitution for unjust enrichment is an equitable remedy, available only when there is no adequate remedy at law"). Therefore, to the extent the ELMC's unjust enrichment claims are brought under the laws of the states listed in the Charts at 52–56, they must be dismissed.

Moreover, a key requirement of many states' unjust enrichment laws is that the plaintiff must confer a *direct* benefit upon the defendant—something akin to a privity requirement. *See, e.g.*, *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 711 (D.N.J. 2011) (internal quotation marks and citation omitted) ("Since a plaintiff must confer a benefit on the defendant to support an unjust enrichment claim, this element has been interpreted by New Jersey courts as a requirement that

the plaintiff allege a sufficiently direct relationship with the defendant to support the claim"); *In re Packaged Seafood Prod. Antitrust Litig.*, 242 F. Supp. 3d 1033, 1090 (S.D. Cal. 2017) (quoting *Kopel v. Kopel*, 229 So. 3d 812, 818 (Fla. 2017)) (dismissing unjust enrichment claim under Florida law because "the Florida Supreme Court explicitly acknowledged that 'to prevail on an unjust enrichment claim, the plaintiff must directly confer a benefit to the defendant'"); *see also* Charts at 50–51. The ELMC contains no such allegations of any Plaintiff conferring a direct benefit upon any of the Manufacturer Defendants. To the contrary, the ELMC indicates that the Manufacturer Defendants did not sell the products directly to consumers and that Plaintiffs are three transactions removed from the manufacturers. *See* ELMC ¶ 155. That leaves the ELMC without a viable claim for unjust enrichment under the laws of the states listed in the Charts at 50–51.

G. The MMMC Fails to Allege a Claim for Medical Monitoring.

In the MMMC, Plaintiffs pursue a stand-alone medical monitoring cause of action, despite the vast majority of states either refusing to recognize medical monitoring as an independent cause of action or recognizing medical monitoring only as a measure of recoverable damages. Twenty states do not recognize medical monitoring claims at all. *See* Charts at 57–58. For this reason, medical monitoring claims brought under the laws of the states listed in Charts at 57–58 should be dismissed. Nine states (and Puerto Rico) have not recognized medical monitoring as

an independent cause of action. *See* Charts at 59. For this reason, the medical monitoring claims brought under the law of the states listed in Charts at 59 should be dismissed. Fourteen states permit the recovery of damages for medical monitoring costs but still refuse to recognize medical monitoring as an intendent cause of action. *See* Charts at 60. For this reason, the medical monitoring claims brought under the law of the states listed in Charts at 60 should be dismissed.

H. The PIMC's Claims for Wrongful Death, Survival Actions and Loss of Consortium, and Demand for Punitive Damages, Fail as a Matter of Law

1. The PIMC's Claims for Wrongful Death, Survival Actions, and Loss of Consortium Should Be Dismissed

The PIMC asserts three derivative claims: (1) wrongful death; (2) survival actions; and (3) loss of consortium. PIMC ¶¶ 580–587, 588–592, 593–600. Because each claim is derivative, it should be dismissed for the same reasons as the PIMC's underlying claims on which each derivative claim relies. *See Marie v. McGreevey*, 314 F.3d 136, 140 (3d Cir. 2002) (quoting *Giardina v. Bennett*, 545 A.2d 139, 145 (N.J. 1988)) (wrongful death); *Pisano v. Extendicare Homes, Inc.*, 77 A.3d 651, 659–660 (Pa. Super. Ct. 2013) (wrongful death and survival); *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 777–778 (3d Cir. 2018) (loss of consortium).

2. The PIMC Does Not State a Plausible Claim for Punitive Damages.

The PIMC fails to allege any plausible factual basis supporting its claim for punitive damages, even under the most lenient standard among those states that

might consider such damages.[49] An action for punitive damages, like any other, must allege a claim for relief that is plausible on its face. *See, e.g.*, *Shukh v. Seagate Tech., LLC*, 873 F. Supp. 2d 1087, 1091 (D. Minn. 2012) (citing *Twombly* and *Iqbal*); *Kelley v. Corrections Corp. of Am.*, 750 F. Supp. 2d 1132, 1147 (E.D. Cal. 2010) (citing *Twombly* and *Iqbal*).

Asserting a claim for punitive damages requires, *at a minimum*, that the PIMC present facts which, if accepted as true, demonstrate gross negligence on the part of Defendants, and only a minority of States permit punitive damages for gross negligence.[50] *See* Charts at 61–67. In New Jersey, for example, punitive damages require clear and convincing evidence that the defendant's acts or omissions "were actuated by actual malice or accompanied by a wanton and willful disregard of persons," and "may not be satisfied by proof of any degree of negligence including gross negligence." N.J.S.A. § 2A:15–5.12(a). Those states applying a gross negligence standard define it differently, but all require conduct a degree of

[49] A plaintiff's ability to assert a claim for punitive damages and the standard to plead such a punitive damages claim where available are questions of law that vary by state. Defendants reserve their right to contest punitive damages as to individual plaintiffs on jurisdiction-specific grounds.

[50] Though many states impose a higher standard, the minimum standard of any state for punitive damages requires that Plaintiffs plead facts sufficient to establish gross negligence. *See* Charts at 61–67. The statutory standard for a punitive damages claim is significantly higher in most states, and some do not permit punitive damages at all. *See id.*

magnitude beyond ordinary negligence. *See, e.g.*, *Mobil Oil Corporation v. Ellender*, 968 S.W.2d 917, 921 (Tex. 1998) (finding gross negligence to support punitive damages requires "an extreme degree of risk" "actual, subjective awareness of the risk involved," and "conscious indifference to the rights, safety, or welfare of others"); *Kinney v. Butcher*, 131 S.W.3d 357, 359 (Ky. Ct. App. 2004) (defining gross negligence to award punitive damages as a "wanton or reckless disregard for the safety of others"); *see also* Fla. Stat. § 768.72(2)(b) (defining "gross negligence" for punitive damages as conduct "so reckless or wanting in care that it constitutes a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct").

The PIMC's punitive damages claim, even viewed liberally, does not plead facts asserting grossly negligent conduct. The PIMC alleges Defendants failed to conduct proper quality control, testing, and post-market surveillance, purportedly resulting in VCDs containing "unreasonably dangerous and carcinogenic substances" being distributed without disclosure of their alleged dangerousness. PIMC ¶¶ 602–608, 609–611. Its allegations are merely a redux of the PIMC's earlier claims with no plausible factual allegations of gross negligence, much less conduct capable of satisfying any higher punitive damages standard. The PIMC does not allege that Defendants engaged in any extreme departure from the ordinary standard of conduct. Instead, the PMIC contains conclusory statements as to Defendants'

supposed knowledge of nitrosamine contamination, but supplies no allegations of fact in support. *See* PIMC ¶¶ 11, 14, 168. The PIMC asks the Court to impute knowledge or intent to Defendants based on a series of unrelated factual allegations pertaining to a single API manufacturing site (*see id.* ¶¶ 197–198), but these statements, even if accepted as true, connect only tangentially to the VCD manufacturing process at issue in this litigation. The same goes for the PIMC's allegations regarding Ranbaxy, a prior manufacturer of Diovan and non-party to this litigation (*see id.* ¶¶ 252–262), and regarding purported issues with the Defendants' manufacturing practices either unrelated to the VCD manufacturing process or occurring after the recalls had been initiated (*see id.* ¶¶ 271–285, 289–300, 311–330, 334–344).

Put simply, the PIMC's conclusory general allegations lack sufficient facts to cross the threshold of gross negligence and to state a claim for punitive damages under even the most permissive standard. *See id.* ¶¶ 413–426. Without such factual allegations, the PIMC's claims cannot clear the high bar to plead punitive damages under the laws of any state, and the claims should therefore be dismissed.

VI. THE COMPLAINTS FAIL TO STATE CLAIMS FOR RELIEF AGAINST FDA LIAISONS.

In addition to joining all arguments for dismissal made by the Manufacturer Defendants, the FDA Liaison Defendants seek dismissal pursuant to Rule 12(b)(6) for Plaintiffs' failure to state cognizable claims against them. APUSA, Hetero USA,

and Prinston are U.S. agents for foreign manufacturers' production of VCDs under 21 C.F.R. § 207.69(b),[51] which effectively makes them liaisons between FDA and the respective foreign manufacturers.

A U.S. agent possesses limited responsibilities to serve as a liaison to FDA on behalf of a foreign establishment.[52] Defendants are unaware of any case law holding a U.S. agent liable for claims arising from a foreign establishment's manufacturing or sale of medications. Rather, in *Moore*, the court dismissed claims against a foreign vaccine manufacturer's U.S. agent because it "did not manufacture, distribute, promote, sell, administer, or provide the package warnings or inserts." *Moore v. Medeva Pharms., Inc*., No. 01-311-M, 2004 WL 57084, at *2 (D.N.H. Jan. 13, 2004). The regulations "obligated [the U.S. agent] only to act as an intermediary between the manufacturer and the FDA; the regulations . . . do not purport to impose any further obligations on a United States agent of a foreign drug manufacturer." *Id.* at *3.

[51] 21 C.F.R. § 207.40(c) was the prior U.S. agent provision but it was replaced by 21 C.F.R. § 207.69(b), effective Nov. 29, 2016.

[52] 21 C.F.R. § 207.69(b) charges a U.S. agent with: (1) routing and responding to FDA communications; (2) responding to questions concerning drugs imported or offered for import to the U.S.; (3) assisting in scheduling FDA inspections; and (4) receiving information/documents from FDA for the foreign establishment.

The Complaints' allegations that Hetero USA and Prinston are potentially liable for engaging in the manufacturing, sale, and distribution of VCDs are conclusory assertions that "are not entitled to the assumption of truth." *Santiago v. Warminster Tp.*, 629 F.3d 121, 131 (3d Cir. 2010) (quoting *Iqbal*, 556 U.S. at 680). Likewise, the allegations that APUSA designed, manufactured and tested the VCDs are merely catch-all assertions. *See id.* The Complaints fail to plead any specific facts that Hetero USA or Prinston designed, manufactured, distributed, or sold the VCDs at issue. Similarly, the Complaints lack factual support to indicate APUSA was responsible for manufacturing, testing, or designing the VCDs at issue. Accordingly, the Court should dismiss all claims against Hetero USA and Prinston, and all claims alleging APUSA designed or manufactured the VCDs.

CONCLUSION

WHEREFORE, for the foregoing reasons, the Manufacturing Defendants respectfully request the Complaints be dismissed.

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Respectfully submitted,

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